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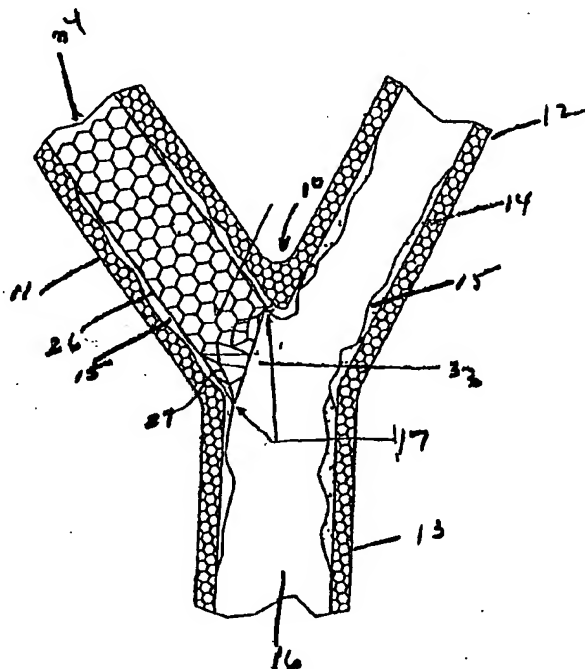
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| (21) International Application Number: PCT/US00/08482 (22) International Filing Date: 29 March 2000 (29.03.00) (30) Priority Data: 60/126,911 30 March 1999 (30.03.99) US (71) Applicant (for all designated States except US): ANGIOLINK CORPORATION [US/US]; 1063 Turnpike Street, Stoughton, MA 02072 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): GIAMBARTOLOMEI, Alessandro [US/US]; 301 Prospect Avenue, Syracuse, NY 13203 (US). EITLINGER, Mark [US/US]; 546 Lowell Street, Lexington, MA 02420 (US). TALLARIDA, Steven, J. [US/US]; 11 Victoria Lane, Mansfield, MA 02048 (US). (74) Agent: PFLEGER, Edmund, Paul; Hayes, Soloway, Hennessey, Grossman & Hage, P.C., 130 W. Cushing Street, Tucson, AZ 85701 (US). | | (81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TO). Published <i>With international search report.</i> |

(54) Title: **ANGULAR VASCULAR STENT**

(57) Abstract

This invention is a method, and device for treating one or more vessels at a bifurcation (10) without blocking or restricting the flow of blood; an expandable and deformable stent (25) having a cylindrical body; and an angled portion (27) at one or both ends. The angled stent (25) is located, and oriented at the bifurcation (10) so that when expanded the cylindrical body and the angled proximal end (27) fully support the first vessel without compromising or interfering with the second vessel. One or more of such angled stent (25) may be deployed at a bifurcation (10).



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Descripti n

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1 ANGULAR VASCULAR STENT**2 FIELD OF THE INVENTION**

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3 The present invention relates to stent to be used in a bifurcating vessel, and,
4 more particularly, to an expandable and deformable stent having a cylindrical body
5 and an angled portion at one or both ends and a method for using same.

6 BACKGROUND OF THE INVENTION

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7 A stent is used for treating occlusions, stenoses, or aneurysms in a blood
8 vessel. Typically, the stent is compressed and implanted in a blood vessel, artery or
9 vein, at the site of the stenosis or other restriction to reinforce and support collapsing,
10 occluded or weakened sections of the vessel. Once in position in the blood vessel,
11 the stent is expanded, dilating the vessel at the site and enabling the blood to flow
12 more freely through the vessel.

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13 While generally satisfactory for the treatment of sites in continuous or
14 unbifurcated portions of the vessels, arteries or veins, prior art stents are not well
15 suited where the site of the desired treatment is located at or across a bifurcation.
16 One of the difficulties with conventional stents is that they are produced in a straight
17 tubular configuration, employing features with "squared off ends". The implantation
18 of the conventional stent in one branch at or near a bifurcation can result in either
19 positioning a portion of one end of the stent extending into or across the bifurcation
20 thereby obstructing or compromising the other branch and/or the bifurcation,
21 restricting the blood flow and leading to an unfavorable result. On the other hand,
22 by locating the other end of the stent sufficiently away from the bifurcation so as not
23 to interfere with or obstruct the other branch, the damaged or diseased bifurcating
24 vessel is not fully treated.

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25 U.S. Patent No. 4,994,071 discloses a bifurcating stent which includes a
26 structure, particularly a series of interconnected loops defining a first flow path and an
27 additional structure, using a second series of interconnected loops defining a second
28 branching flow path. An interconnection joins the structures that define the first and
29 second flow paths which is then bent to conform to the shape of the vessel.

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30 U.S. Patent No. 5,607,444 discloses an expandable stent which is constituted
31 of a tubular member having a portion that is flared. The stent is placed within the
32 bifurcated vessel to be repaired with the flared portion extending beyond the junction

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1 of the bifurcation and into the other branch. The flared portion is then "capped" or
2 folded back along the wall of the other branch at the bifurcation.

3 U.S. Patent No. 5,938,696 discloses stents for use at a bifurcation comprised
4 of a first stent including a proximal engaging portion which may be flared and a
5 second stent providing a cooperating portion to accept the engaging portion. In use at
6 least one of the stents extends across the bifurcation into another branch vessel.

7 However, the prior art stents do not satisfactorily correct the stenosis at the
8 bifurcation. In order to overcome these problems, a stent that will expand in
9 juxtaposition with a bifurcation, treating the entire damaged or diseased vessel and
10 without extending into the bifurcation or overlapping into the other branch, without
11 restricting or blocking the pathway or risking damage to the bifurcation and other
12 branch is needed.

13 SUMMARY OF THE INVENTION

14 The present invention is directed to an angled stent device for treating one or
15 more vessels at a bifurcation without blocking or restricting access or blood flow to
16 the bifurcation or other vessels. The invention also provides a method for using the
17 stent.

18 The stent is comprised of an expandable cylindrical portion and an angled
19 portion at one or both ends. The stent is constructed of a material capable of radial
20 expansion and having sufficient strength to retain its shape after expansion and to
21 support the most proximal end of the angled portion. In the preferred embodiment,
22 the cylindrical portion has a symmetrical geometric pattern which facilitates the
23 expansion while providing the required strength. The angled portion of the stent
24 extends from the cylindrical portion, the angled portion being configured at an angle
25 substantially approximating the angle established at the bifurcation by the junction of
26 the bifurcated vessel and the other branch, once expanded. The expansion of the
27 angled portion at or near the bifurcation is consistent with the expansion of the
28 cylindrical portion. Preferably, the angled portion has an asymmetrical geometric
29 pattern and is constructed of the same material as the cylindrical portion.
30 Alternatively, the angled portion may be constructed of a different material or may be
31 implanted apart from the cylindrical portion.

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1 A preferred use of the angled stent is accomplished by means of a balloon
2 catheter. The stent is arranged coaxially on the balloon with the angled portion on
3 the proximal portion of the balloon and the cylindrical portion on the distal portion of
4 the balloon. Alternatively, depending upon the introduction of the stent at the
5 bifurcation, these position can be reversed. The balloon-stent assembly is arranged
6 on the catheter and is advanced to the location of treatment within the vessel. In the
7 preferred embodiment, a radio-opaque marker is arranged on one end of the balloon
8 adjacent to the angled portion of the stent. A buttress or stop cap is arranged on the
9 on the distal end of the balloon to retain the stent in position on the balloon. The
10 desired location and orientation of the balloon-stent assembly is achieved by means
11 of radiography. Once the balloon-stent assembly is in position, the balloon is
12 expanded, deploying the expanded stent within the vessel such that of the angled
13 portion is in juxtaposition with the bifurcation and together with the cylindrical
14 portion fully supports the damaged or diseased portion of the bifurcated vessel
15 without extending across or into the bifurcation or the other vessel. Following
16 deployment of the stent, the balloon is deflated and the balloon, radio-opaque marker,
17 stop cap and catheter are removed from the patient.

18 It will be appreciated that a stent according to the invention would have the
19 advantage of fully treating the damaged or diseased vessel at or near the bifurcation
20 without compromising or obstructing the blood flow in other portions of the
21 bifurcation. A further advantage is that such stent will allow access to and will not
22 interfere with any treatment introduced or delivered to the bifurcation or other vessel.
23 Another advantage of a stent according to the invention is that such stents, having the
24 same or different angles or shapes, or combination of angles or shapes, for example
25 frustoconical, at one end may be used in more than one branch at a bifurcation
26 without extending into, obstructing or compromising the bifurcation, and without
27 overlapping an adjacent branch or stent.

28 These and other objects, features and advantages of the present invention will
29 be better understood with reference to the detailed description of the preferred
30 embodiment and the accompanying drawings.

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1 BRIEF DESCRIPTION OF THE DRAWINGS

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2 FIGS. 1a and 1b show conventional stent devices of the prior art in an
3 expanded configuration at a bifurcation;

4 FIG. 2 is a side view of one embodiment of the angled stent device of the
5 present invention in an unexpanded configuration;

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6 FIG. 3 is a side view of the unexpanded angled stent according to the present
7 invention arranged on a balloon catheter;

8 FIG. 4 shows a side view of the unexpanded angled stent of FIGS. 2 and 3,
9 illustrating a preferred method of placement of the stent at a bifurcation;

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10 FIG. 5 shows one embodiment of the angled stent device of the present
11 invention in an expanded configuration;

12 FIGS. 6 and 7 are side views of alternative embodiments of the present
13 invention;

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14 FIG. 8 shows another embodiment of the present invention.

15 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

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16 The present invention includes a device and method for treating one or more
17 vessels at a bifurcation without blocking or restricting access or blood flow to the
18 bifurcation or other vessels.

19 As shown in FIGS. 1a and 1b conventional stents 5 are produced in a straight
20 tubular configuration having squared off ends 3. FIG. 1a depicts conventional stent 5
21 in its expanded form, implanted in a bifurcated vessel 11 at or near a bifurcation 10
22 opening up the restriction to interior arterial passage 16 caused by stenosis 15 and
23 providing support for the vascular wall 14. By attempting to fully treat the diseased
24 or damaged vessel 11, proximal end 33 of conventional stent 5 extends into the
25 bifurcation 10 and junction 17 thereby obstructing branches 12, 13, restricting the
26 blood flow. FIG. 1b shows prior art stent 5 after expansion, positioned in bifurcated
27 vessel 11 with the end 33 sufficiently remote from the bifurcation 10 and junction 17
28 so as not to extend into the bifurcation. However, the damaged or diseased bifurcated
29 vessel 11 is not fully treated as the stent 5 does not reach portions of junction 17 of
30 the bifurcation.

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1 An angular stent 25 according to the present invention which is depicted in
2 FIG. 2 provides for the complete treatment of a diseased or damaged bifurcated vessel
3 without obstructing the bifurcation.

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4 As shown in FIG. 2, angular stent 25 is comprised of expandable cylindrical
5 portion 26 and expandable angled portion 27 at the proximal end 33. Preferably, the
6 angular stent 25 is constructed of a material capable of radial expansion and having
7 sufficient strength to retain its shape after expansion and to support the most proximal
8 end of the angled portion 27. In the preferred embodiment, the cylindrical portion 26
9 has a symmetrical geometric pattern which facilitates the expansion while providing
10 the required strength. The angled portion 27 of stent 25 extends from cylindrical
11 portion 26, substantially parallel to longitudinal axis 28, end 33 of the angled portion
12 27 being configured at an angle substantially approximating the angle established at
13 the bifurcation 10 by the junction 17 of the bifurcated vessel 11 and the other
14 branches 12, 13, once expanded. The expansion of the angled portion 27 at or near
15 the bifurcation 10 is consistent with the expansion of the cylindrical portion 26 of the
16 stent. Advantageously, the stent may be produced having any angle or combination
17 of angles at one or both ends. Accordingly, the stent and or angled portion of the
18 stent best approximating the angle established by the junction of the vessel or vessels
19 to be treated and the other branch or branches of the bifurcation may be selected for
20 implantation.

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21 Preferably, the angled portion 27 has an asymmetrical geometric pattern and is
22 constructed of the same material as the cylindrical portion 26. Alternatively, the
23 angled portion may be constructed of a different material or may be implanted apart
24 from the cylindrical portion.

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25 A preferred use of the angled stent 25 according to the invention is
26 accomplished by means of a balloon catheter 35. Unexpanded stent 25 is arranged
27 coaxially on balloon 32 with the angled portion 27 at end 33 portion of the balloon 32
28 and the cylindrical portion 26 of the stent 25 at the distal portion 34 of the balloon.
29 Tubular portion 36 extends from the end of balloon 32 as a conduit allowing for
30 inflation and deflation. Guide wire 29 extends the length tubular portion 36 and
31 balloon 32. In the preferred embodiment, expandable radio-opaque marker 30 is
32 arranged at the end 33 of the balloon 32 adjacent to the angled portion 27 of the stent

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1 25, the adjacent end of the marker 30' being angled correspondent to the end of
2 angled portion of the stent. Proximal angular stop 30' may be arranged on balloon 32
3 between the end of the angled portion 27 and the radio-opaque marker 30' to maintain
4 the alignment and positioning of the stent 25 on the balloon catheter 35. A buttress
5 or stop cap 31, which may also be radio-opaque, is arranged on the on the distal end 34
6 of the balloon 32 to retain the stent 25 in position on the balloon. Further, the radio-
7 opaque marker 30' and buttress or stop cap 31 enable the physician or radiographer to
8 observe the placement and orientation of the stent and balloon catheter assembly
9 within the arterial passageway and the bifurcated vessel.

10 As shown in FIG. 4, the unexpanded stent 25 and balloon catheter 35
11 assembly is advanced, for example, through interior arterial passageway 16, to the
12 intended location of treatment within the bifurcated vessel 11. By use of radiography,
13 the radio-opaque marker 30' and the stop cap 31 are observed and the unexpanded
14 angular stent 25 is advanced into the desired position within the bifurcated vessel 11.
15 Once the stent 25 is in position balloon 32 is expanded, deploying the expanded
16 angular stent 25 within the vessel 11 such that the end 33 of the angled portion 27 of
17 the stent is in juxtaposition with junction 17 of bifurcation 10 and together with the
18 cylindrical portion 26 fully supports the damaged or diseased portion of the bifurcated
19 vessel 11 without extending across or into the bifurcation 10 or the other vessels 12,
20 13. Following expansion and deployment of the stent, the balloon is deflated and the
21 balloon, radio-opaque marker, stop cap and catheter are removed from the patient, as
22 shown in FIG. 5. In this way diseased or damaged vessel 11 is completely treated and
23 blood flow is not obstructed or restricted by any portion of the stent or overlapping,
24 allowing access for any treatment introduced or delivered to the bifurcation or other
25 vessels without interference. Alternatively, depending upon the introduction of the
26 stent to the bifurcation 10, the arrangement of the stent, the radio-opaque marker and
27 the stop cap on the balloon catheter may be reversed.

28 Another embodiment of the present invention is the use of angular stents in
29 two branches of the bifurcation. FIG. 6 shows a dual stent application in accordance
30 with the invention. Similar to the implantation of angled stent 25 in the bifurcated
31 vessel 11 as depicted in FIGS. 3 and 4, the angular stents in a dual application may
32 completely treat the diseased or damaged sites without interfering with or overlapping

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1 the other stent and without extending into the bifurcation or otherwise obstructing or
2 restricting the blood flow.

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3 FIG. 7 depicts another embodiment, an angular stent 25 according to the
4 invention, after expansion is in position in the bifurcated vessel 11 and a conventional
5 stent 5, is implanted in the bifurcation. In this way the bifurcation is treated and the
6 stents are not compromised.

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7 In another embodiment, an example of additional or subsequent treatment to a
8 repaired bifurcation area is shown. FIG. 8 shows dual angular stents 25 implanted
9 and deployed in branches 11 and 12. Stent 25' including an angled portion 27 having
10 a frustoconical configuration 40 is implanted in other branch 13. Although the end 40
11 of the angled portion of stent 25' extends into the bifurcation, as a result of the
12 configuration of the angled stents the diseased or damaged vessels are completely
13 treated without any such stent obstructing or compromising the bifurcation or
14 overlapping an adjacent branch or stent.

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15 It will be appreciated that the angular stent according to the invention enable
16 full treatment of the damaged or diseased vessel at or near the bifurcation without
17 compromising or obstructing the blood flow in other portions of the bifurcation
18 vessel. It will also be appreciated that the angular stent according to the invention
19 may be produced having a variety of angles or combination of angles or shapes, and
20 may be used in more than one branch at a bifurcation without extending into,
21 obstructing or compromising the bifurcation, and without overlapping an adjacent
22 branch or stent.

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23 Although described in terms of the presently preferred embodiment, those
24 skilled in the art will appreciate that the present invention is not limited to the
25 embodiment described.

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Claims

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1 CLAIMS

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2 1. A stent comprising, a cylindrical portion having two ends wherein at least one
3 said end having an angled portion forming an angle with respect to a longitudinal axis
4 of said cylindrical portion.

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5 2. A stent as claimed in claim 1, wherein said cylindrical portion and said angled
6 portion being expandable in a radial direction about said longitudinal axis,

7 3. A stent as claimed in claim 1, wherein said angle approximating an angle
8 established at a bifurcation by a junction of two or more bifurcated vessels.

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9 4 A stent as claimed in claim 1, wherein said cylindrical portion and said angled
10 portion are constructed of a flexible material capable of radial expansion, said
11 material having sufficient strength to retain its shape after expansion and to support
12 the most proximal end of the angled portion.

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13 5. A stent as claimed in claim 1, wherein the cylindrical portion is symmetrical
14 about said longitudinal axis

15 6. A stent as claimed in claim 1, wherein said angled portion expands
16 consistently with the expansion of the cylindrical portion.

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17 7. A stent as claimed in claim 1, wherein the angled portion is constructed of the
18 same material as the cylindrical portion and formed as a single unit.

19 8. A stent as claimed in claim 1, wherein the angled portion is constructed of a
20 different material than the cylindrical portion.

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21 9. A method for using an angular stent, comprising the steps of:

22 arranging an unexpanded stent having a cylindrical portion and an angular
23 portion coaxially on a balloon catheter, the balloon having tubular portion and two
24 end portions;

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25 arranging the cylindrical portion of the stent is on the tubular portion of the
26 balloon;

27 arranging the angled portion of the stent at an end portion of the balloon,

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28 arranging an expandable marker on one end of the balloon adjacent to said
29 angled portion and;

30 arranging an expandable stop cap on the other end portion of the balloon.

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1 10. The method of claim 9, further comprising the step of advancing the
2 unexpanded stent and balloon catheter to an intended location in a vessel and
3 positioning said stent by observing the expandable marker and the stop cap.

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4 11. The method of claim 9, further comprising the step of expanding the balloon
5 and deploying the expanded angular stent such that the end of the angled portion of
6 the stent is in juxtaposition with a junction of a bifurcation.

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7 12. The method of claim 9, further comprising the step of deflating the balloon
8 and removing the balloon, expandable marker, expandable stop cap and catheter are
9 from the patient.

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10 13. The method of claim 9, wherein the expandable marker and/or the expandable
11 stop cap are radio-opaque.

12 14. The method of claim 9, wherein the expandable marker is arranged on the end
13 portion of the balloon.

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14 15. The method of claim 9, wherein the adjacent end of the expandable marker is
15 angled correspondent to the end of angled portion of the stent.

16 16. The method of claim 9, wherein the expandable marker is arranged on the
17 distal end portion of the balloon.

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18 17. The method of claim 9, wherein the adjacent end of the expandable marker is
19 angled with respect to the distal end of angled portion of the stent.

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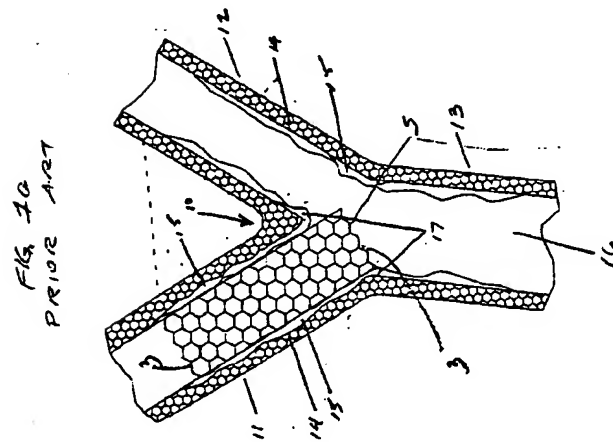
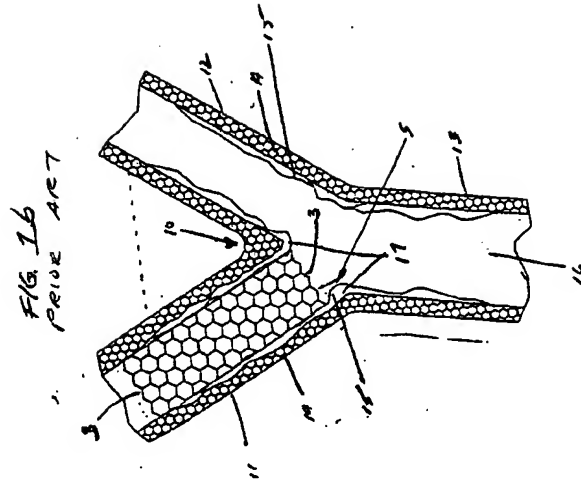


FIG. 2.

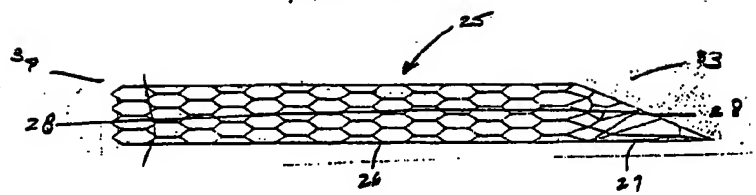
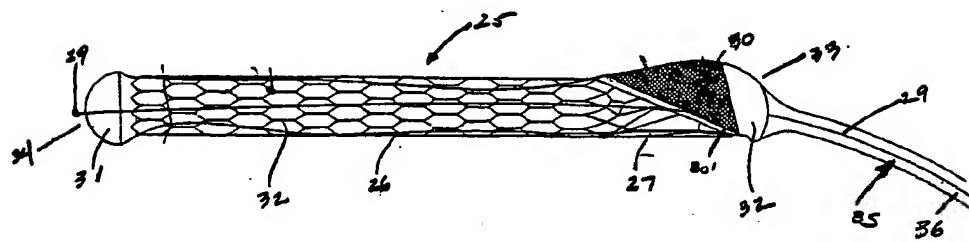
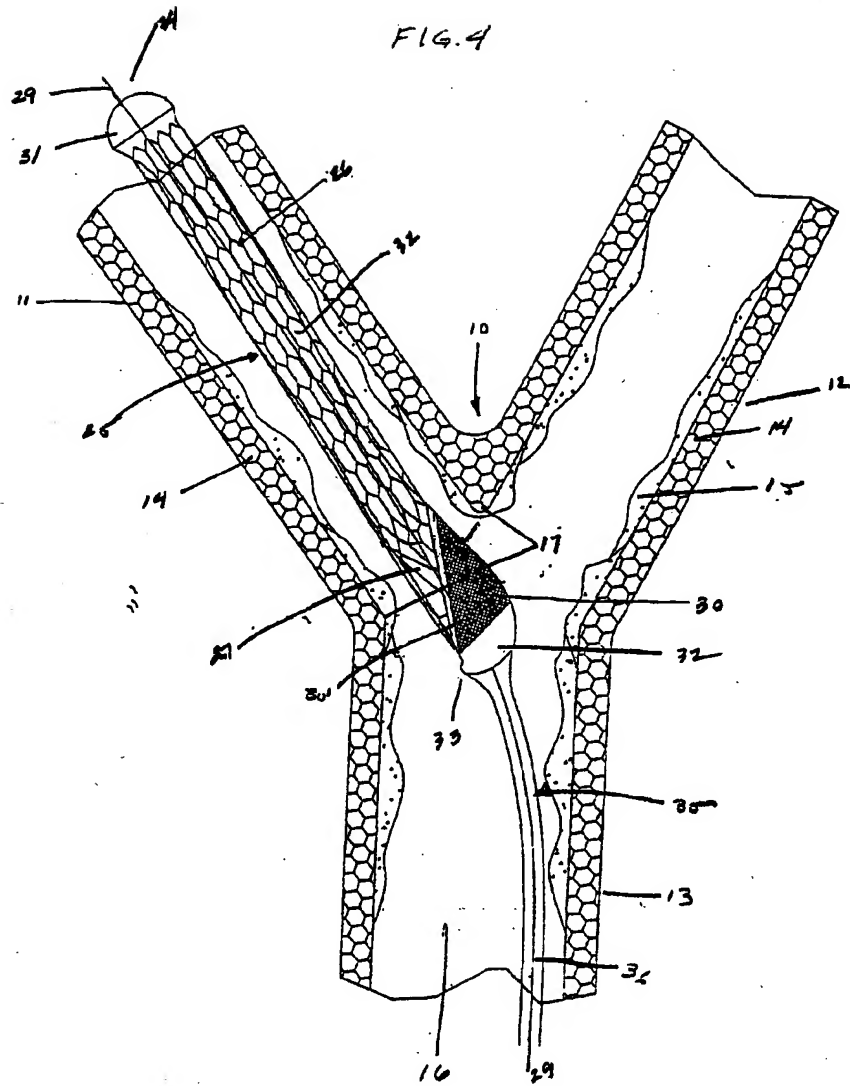
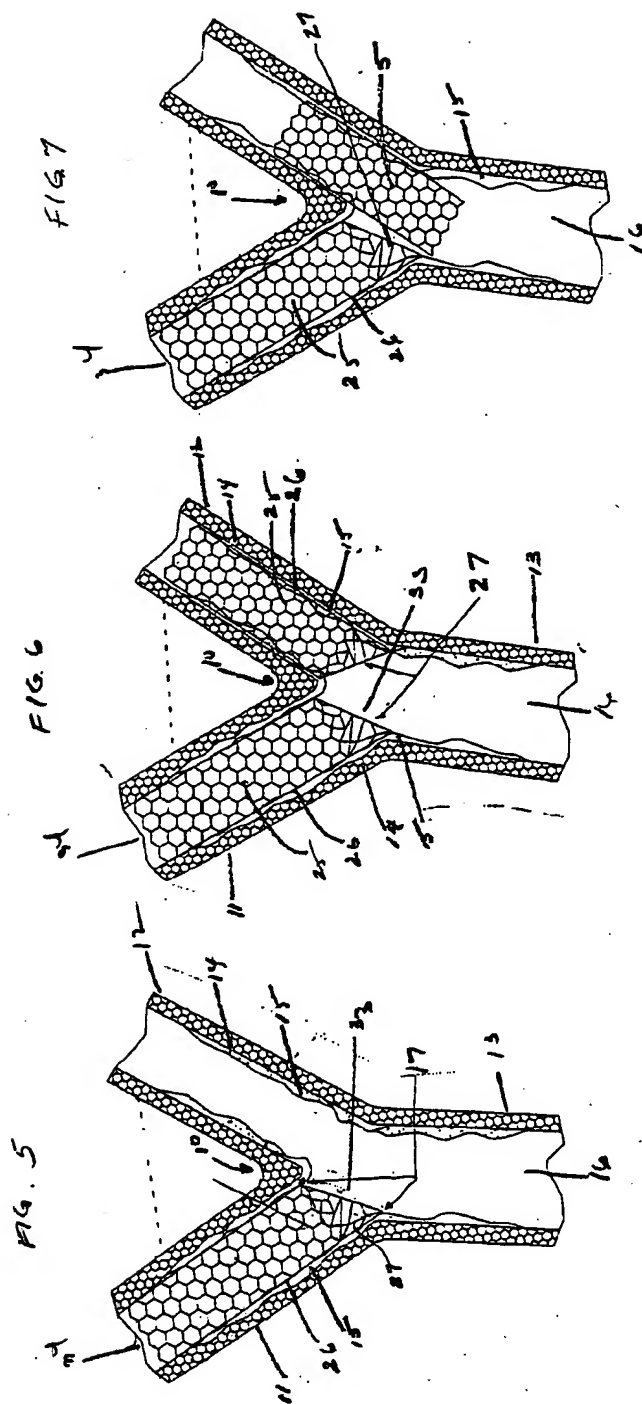


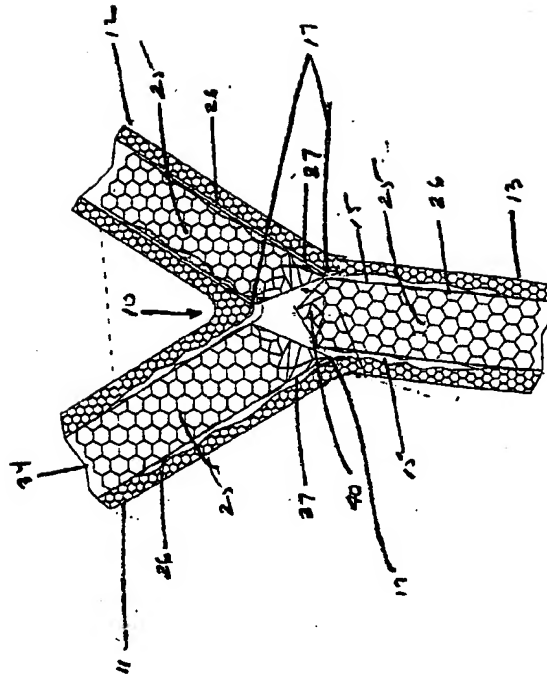
FIG 3







Figs. 8



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/08482

| | | |
|---|--|-----------------------|
| A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61F 2/00 US CL : 623/1 According to International Patent Classification (IPC) or to both national classification and IPC | | |
| B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 623/1, 11, 12 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) | | |
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| A, P | US 5,893,887 A (JAYARAMAN) 13 April 1999, entire document. | 1-17 |
| A, P | US 5,906,640 A (PENN et al.) 25 May 1999, entire document. | 1-17 |
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